

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for:**

**Application Number : 040039**

**Trade Name : TRIAMCINOLONE ACETONIDE CREAM  
USO 0.1%**

**Generic Name: Triamcinolone Acetonide Cream USP 0.1%**

**Sponsor : Taro Pharmaceuticals USA, Inc.**

**Approval Date: November 26, 1997**

# CENTER FOR DRUG EVALUATION AND RESEARCH

**APPLICATION**                      **040039**

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<b>Tentative Approval Letter</b>				
<b>Approvable Letter</b>				
<b>Final Printed Labeling</b>	<b>X</b>			
<b>Medical Review(s)</b>				
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**Application Number** **040039**

**APPROVAL LETTER**

ANDA 40-039

NOV 26 1997

Taro Pharmaceuticals USA, Inc.  
Attention: Lorraine W. Sachs  
U.S. Agent for: Taro Pharmaceuticals Inc.  
5 Skyline Drive  
Hawthorne, NY 10532  
|||||

Dear Madam:

This is in reference to your abbreviated new drug application dated December 23, 1991, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Triamcinolone Acetonide Cream USP, 0.1%.

Reference is also made to your amendments dated March 18, July 25, September 19, September 29, and October 29, 1997.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Triamcinolone Acetonide Cream USP, 0.1% to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Kenalog Cream, 0.1% of ApotHecon Inc.).

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-240). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-240) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

/S/

Douglas L. Sporn  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research

11/26/97

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**APPLICATION NUMBER**      **040039**

**FINAL PRINTED LABELING**

Directions for puncturing tube seal:  
Remove cap. Turn cap upside down and place  
puncture tip onto tube. Push cap until tube end is  
punctured. Screw cap back on to reseal tube.

Mfd. by: TARO Pharmaceuticals Inc.,  
Downsview, Ontario, Canada M3J 2M4  
Dist. by: TARO Pharmaceuticals U.S.A., Inc.,  
Hawthorne, NY 10532



N 3 51672-1282-8 9

80 g

## Triamcinolone Acetonide Cream USP, 0.1%

NDC 51672-1282-8

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

**CAUTION: Federal law prohibits dispensing without prescription.**  
Keep this and all medication out of the reach of children.

**EACH GRAM CONTAINS:** 1 mg triamcinolone acetonide in a cream base consisting of cetyl alcohol,  
glyceryl monostearate, cetyl esters wax, isopropyl palmitate, polysorbate-60, polysorbate-80,  
propylene glycol and purified water.

**USUAL DOSAGE:** Apply to the affected area two or three times daily. See insert.

Store at controlled room temperature 15° - 30°C (59° - 86°F); avoid freezing.

Lot No. - Exp. Date, see end flap or crimp of tube.

80 g

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NDC 51672-1282-8

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**Triamcinolone  
Acetonide  
Cream USP,  
0.1%**

80 g

APR 10 2010

*Margo*

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**APPLICATION NUMBER**      **040039**

**CHEMISTRY REVIEW(S)**

1. CHEMISTRY REVIEW NO. 5

2. ANDA # 40-039

3. NAME AND ADDRESS OF APPLICANT

Taro pharmaceuticals Inc.  
130 East Drive  
Bramalea, Ontario  
L6T 1C3 Canada

4. LEGAL BASIS FOR SUBMISSION

See Review # 1

5. SUPPLEMENT(s)

Original 12/23/91

6. PROPRIETARY NAME

N/A

7. NONPROPRIETARY NAME

Triamcinolone Acetonide

8. SUPPLEMENT(s) PROVIDE(s) FOR:

N/A

9. AMENDMENTS AND OTHER DATES:

Amendment 3/18/97  
Amendment 7/25/97  
Amendment 9/19/97  
Amendment 9/29/97  
Amendment 10/29/97

10. PHARMACOLOGICAL CATEGORY

Anti-inflammatory

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

DMF's (b)4 - Confidential Business

13. DOSAGE FORM

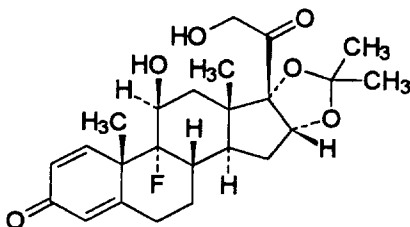
Cream

14. POTENCY

0.1%

15. CHEMICAL NAME AND STRUCTURE

Triamcinolone Acetonide.  $C_{24}H_{31}FO_6$ . 434.51. Pregna-1,4-diene-3,20-dione, 9-fluoro-11,21-dihydroxy-16,17-[(1-methylethylidene)bis(oxy)]-, (11 $\beta$ ,16 $\alpha$ )-. 76-25-5.



17. COMMENTS

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable.

19. REVIEWER: DATE COMPLETED:

Nashed E. Nashed, Ph.D.

10/1/97

cc: ANDA 40-039  
Division File  
Field Copy

Endorsements:

HFD-627/NNashed/10/30/97

HFD-627/PSchwartz/10/30/97

X:\NEW\FIRMS\NZ\TARO\LTRS&REV\40-039.6

F/t by: gp/11/7/97

*Handwritten:* 11/7/96  
PS 11/7/97

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**APPLICATION NUMBER**      **040039**

**BIOEQUIVALENCE REVIEW(S)**

FEB 25 1992



Triamcinolone Acetonide Cream, USP  
0.025%, ANDA #40-038  
0.1%, ANDA #40-039  
Reviewer: James Chaney  
WP #40038&9W.D91

Taro Pharmaceuticals, Inc.  
Ontario, Canada  
Submission Date:  
December 23, 1991

Reviews of Two Waiver Requests

The firm has requested a waiver of in-vivo bioequivalence study requirements for its 0.025% and 0.1% triamcinolone acetonide creams. These products are indicated for skin rashes and itches. The listed reference products are 0.025% and 0.1% Kenalog Cream manufactured by Westwood-Squibb Pharmaceuticals. These are pre-1962 drugs which, therefore, are entitled to waivers of in-vivo bioequivalence requirements under CFR 320.22 (b)(2). They are coded AT in the Therapeutic Equivalence List suggesting no known or suspected bioequivalence problems. The reference and test products are intended for identical indications. The test products contain the same active ingredient in identical strengths to the corresponding reference products. The compositions of the formulations for the test products are as follows:

Ingredient:

	0.025% Cream (mg/g)	0.1% Cream (mg/g)
Cetyl Alcohol, NF		
Glceryl Monostearate, BP		
Cetyl Esters Wax, NF		
Isopropyl Palmitate, NF		
Polysorbate-60, NF		
Polysorbate-80, NF		
Propylene Glycol, NF		
Purified Water, USP		
Triamcinolone Acetonide, USP	0.250	1.000

Recommendation:

The Division of Bioequivalence agrees that the information submitted by Taro Pharmaceuticals, Inc. demonstrates that its triamcinolone acetonide creams, 0.025% and 0.1%, fall under CFR Section 320.22 (b)(2) of the Bioavailability/Bioequivalence Regulations. The waivers of in-vivo bioequivalence study requirements for the 0.025% and 0.1% creams of the test product are granted. The 0.025% and 0.1% topical creams of the test product are deemed bioequivalent to Kenalog Cream, 0.025% and 0.1%, respectively, manufactured by Westwood-Squibb Pharmaceuticals.

The firm should be informed of the recommendations.

/S/

James E. Chaney, Ph.D.  
Division of Bioequivalence  
Review Branch I

RD INITIALED A. Wu  
FT INITIALED A. Wu

/S/

for A.I. Mu

cc: ANDA #'S 40-038, 40-039 original, HFD-604(Hare),  
HFC-130 (Allen), HFD-652 (Wu, Chaney), Drug File

JEC/022092/ntp/022492/WP#40038&9W.D91